REMARKS

Claims 1, 2 and 5-37 are pending in the subject application. Claims -- have been amended for clarification purposes. Support for the amendments to claims 1--is found throughout the Specification, as filed, and no new matter is presented by the amendment.

Favorable reconsideration in light of the amendments and remarks which follow s respectfully requested.

1. 35 U.S.C. §112 Rejections

Claims 5-8, 19-32 and 34-47 have been rejected under 35 U.S.C §112, second paragraph, as being indefinite. In particular, the Office objected to the term "releasably" in claims 5, 19, 25, 26, 34, 26 and 37. Applicants have deleted this term from the claims. Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. §102 Rejections

ANDERSON

Claims 1, 2 and 5-37 have been rejected under 35 U.S.C §102(b) over Anderson. In particular, the Office asserts:

> Anderson (795) discloses a method and apparatus for blood collection. A shield/cradle member (21) comprises a trough (Applicants' recess) made of a needle resistant material. The clamping mechanisms are separate from the shield-cradle member (21). Figure 6 shows that the shield/cradle member extends and ends, shown generally at (23) and (29), before meeting either clamping mechanism. The clamping mechanisms are separately attached to flanges by a rivet. See col. 5, ll. 11-39. Figure 1 illustrates stabilizing a body portion within the shield/cradle member (21) solely using a digit of a user's hand and inserting an insertion member (60) of a blood extraction device (1). Stopping the withdrawal of blood, withdrawing the insertion member and removing the body portion from the shield are considered inherent steps that the patient would have to take to complete the method.

Applicants respectfully traverse.

Applicants claim, in amended claim 19, a shielding device comprising: a cradle member being configured so one portion thereof is held in a hand of a user, so another portion thereof receives the body portion, and so a digit of the user's hand secures and stabilizes the body portion in the another portion while holding the cradle member. As specified, the shielding device does not include any type of fastening mechanism. As such, the digit of the user's hand solely fastens the body portion to the cradle member.

Applicants claim, in claim 25, an apparatus for extracting cord blood from an umbilical cord comprising: a shielding device comprising a cradle member being configured and arranged so one portion thereof is held in a hand of a user, so another portion thereof receives the umbilical cord, and so a digit of the user's hand secures and stabilizes the umbilical cord in said another portion while holding the cradle member and a blood extraction device including an insertion member being configured so as to be inserted into the umbilical cord and to withdraw cord blood therefrom. As specified, the shielding member is devoid of mechanisms for fastening the umbilical cord to the shielding member.

Applicants claim, in claim 26, a blood collection device kit comprising: a shielding device including a cradle member, said cradle member being configured and arranged so one portion thereof is held in a hand of a user, so another portion thereof receives the body portion, and so a digit of the user's hand secures and stabilizes the body portion in said another portion while holding the cradle member. As specified, the shielding device is devoid mechanisms for fastening the body portion to the shielding member.

Applicants claim, in claim 36, a shielding device comprising: a cradle member being configured so one portion thereof is held in a hand of a user, so another portion thereof receives the body portion, and so a digit of the user's hand secures the body portion in the another portion while holding the cradle member. Further, said another portion includes a surface recess extending along an axis of the cradle member, in which recess is received the body portion. The recess and said one portion are configured so as to be arcuate in cross-section. Further, the shielding device does not include portions for fastening the body member to the shielding device.

Applicants claim, in claim 37, a cord blood collection device kit comprising: a shielding device including a cradle member, the cradle member being configured and arranged so one portion thereof is held in a hand of a user, so another portion thereof receives an umbilical cord, and so a digit of the user's hand secures and stabilizes the umbilical cord in said another portion while holding the cradle member; a needle and syringe to withdraw cord blood from the umbilical cord, the needle being configures to be inserted into the umbilical cord. Further, said another portion includes a surface recess extending along an axis of the cradle member that is configures and arranged to receive the umbilical cord therein. The recess is arcuate in cross-section. As specified, the shielding device does not include portions for fastening the umbilical cord to the shielding device.

Thus, Applicants device is devoid of any fastening means that would fasten the umbilical cord to the device. According to Applicants' method for collecting blood, the umbilical cord is placed in the device and the user stabilizes the umbilical cord within the device solely using his or her digit. This is a significant advantage in that Applicants' device is very simple in design and, thus, inexpensive and easy to manufacture and very easy to use. To use the device, a user simply places the umbilical cord in the shield member/cradle member, uses a finger to secure the cord, and withdraws blood. The umbilical cord can then be released from the shield member/cradle member by simply releasing the user's finger from the cord. This is a very simple and quick procedure, which is of great importance in a medical procedure such as that involved when delivering one or more babies. The collection of the blood can occur in minimal time using a very simple procedure. Further, because there are no fastening means, during manufacture, there is reduced potential for the production of defective devices. In particular, Applicants' device is very simple to manufacture and would result in minimal defective devices. Other devices having fastening means greatly increase the likelihood that defective devices will be produced (potential for defective clamping means, flanges, shafts, caps, etc. as with Anderson), which would result in significant waste if the devices must be discarded and extra costs and time required to fix the defective devices if not discarded.

This is unlike the device described by Anderson. Anderson describes a complex device wherein a trough 21 receives the umbilical cord and wherein umbilical cord clamps 26, 32 located on opposite ends of the trough 21 clamp and restrict the umbilical cord. Thus, the device described by Anderson includes complex clamps that require additional time and expense to manufacture and assemble. These clamps must be subjected to some type of a quality control to ensure that they operate properly and, thus, there is a possibility that defective clamps can be produced. This all requires additional time, materials and expense. Further, the use of the device in accordance with Anderson is also more complicated and time consuming than Applicants'. Using Anderson's device and methods, a cord must be inserted into the trough. The cord must be inserted more precisely in the trough such that one end of the umbilical cord (cut end) reaches the clamp so that it can be fastened. The clamps much them be manipulated to fasten the umbilical cord. The blood is withdrawn and the clamps must then be unfastened to release the umbilical cord. As set out above, the speed and simplicity of a medical procedure such as that involved here is of great importance and Anderson's device requires additional time to use and involves a more complex procedure than that taught by Applicant.

Applicants respectfully disagree with the Office's assertion that:

> The clamping mechanisms are separate from the shield-cradle member (21). Figure 6 shows that the shield/cradle member extends and ends, shown generally at (23) and (29), before meeting either clamping mechanism. The clamping mechanisms are separately attached to flanges by a rivet. See col. 5, ll. 11-39.

The clamping mechanisms are <u>not</u> isolated from Anderson's device as suggested by the Office. Rather, the clamping mechanisms are integral parts of the Anderson device and are specifically required in accordance with the teachings of Anderson. As set forth by Anderson:

> In Fig. 6, an <u>umbilical cord holder</u> is shown generally as 20. The umbilical cord holder <u>has a trough 21</u>... A flange 23 extends downward from the first end of the trough 21... A shaft, not shown, extends outward from flange 23 and has a cap 25. Cut-end umbilical cord clamp 26 has a curved end 27 that snap locks around the shaft... The opposite end of the trough <u>has an identical clamping mechanism</u> that is comprised of flange 29, uncut-end umbilical cord clamp 32, circular end, 33, <u>clamping portions 34a and 34b</u>... (Col. 4, line 51 – col. 5, line 2)

Thus, Anderson's device, the umbilical cord holder 20, comprises a trough 21 having a clamping mechanism at each end with clamping portions 27a, 27b, 34a, 34b. Anderson's umbilical cord holder, which would be "equivalent" to Applicant's shielding device, thus, does include fastening mechanisms. In particular, Anderson's device includes all of the elements, including the clamping portions and does not only include the trough. The trough and the clamping portions are all essential features of Anderson's device.

As set forth above, Applicants claim, in claims 19, 25, 26, 36 and 37, devices that are specifically devoid of any fastening means that would fasten the umbilical cord to the device. Anderson's devices, on the other hand specifically require fastening/clamping means.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

It is clear from the foregoing remarks that the above-identified claims are not anticipated by the Anderson reference. Anderson does not describe each and every element of Applicants' claims. In particular, Applicants' claims 19, 25, 26, 36 and 37 specifically require that the device be devoid of fastening means. Anderson, on the other hand, explicitly requires fastening means.

Accordingly, claims 19, 25, 26, 36 and 37 are patentable over Anderson. Claims 20-24 and 27-33 depend from claims 19, 25 and 26 and, likewise, are patentable over Anderson.

Applicants claim in claim 1, a method for collection of blood comprising: positioning a body portion, from which blood is to be withdrawn, within a shield member such that the shield member is generally disposed between the body portion and a hand of a user, stabilizing the body portion within the shield member solely using a digit of the user's hand, and inserting an insertion member of a blood extraction device into the body portion such that the shield member is generally disposed between the insertion member and the user's hand.

Applicants claim, in claim 16, a method for collection of umbilical cord blood comprising: positioning an umbilical cord within a shield member, stabilizing the umbilical cord within the shield member solely using a digit of the user's hand, and contacting the cord with a blood extraction device.

Applicants claim, in claim 34, a method for collection of blood from an umbilical cord (cord blood), comprising: providing a shield member, one portion of which is configured to be held in one hand of a user and another portion of which is configured to receive the umbilical cord, wherein the another portion includes a surface recess extending along an axis of the shield member, in which is received the umbilical cord and wherein the recess and the one portion are each arcuate in cross-section; holding the shield member with one hand of a user; positioning the umbilical cord within the shield member such that the shield member is generally disposed between the umbilical cord and the one hand; stabilizing the umbilical cord within the shield member solely using a digit of the user's hand while holding the shield member using the one hand; inserting an insertion member of a blood extraction device into the umbilical cord using another hand of the user such that the shield member is generally disposed between the insertion member and the one hand; and withdrawing the cord blood from the umbilical using the blood extraction device.

Thus, according to Applicants' method, the umbilical cord is stabilized in the device solely using a digit of the user's hand. This is because, as set forth above, Applicants' device is devoid of any fastening means that would fasten the umbilical cord to the device. Applicants' device and methods for use, thus, provide a significant advantage in that Applicants' device is very simple in design and, thus, inexpensive

and easy to manufacture and very easy to use. To use the device, a user simply places the umbilical cord in the device, uses a finger to secure the cord, and withdraws blood. The umbilical cord can then be released from the device by simply releasing the user's finger from the cord. This is a very simple and quick procedure, which is of great importance in a medical procedure such as that involved when delivering one or more babies.

Anderson, on the other hand, as set forth above, specifically requires clamping mechanisms to hold the umbilical cord within the device. Further, when describing use of the device, Anderson specifically requires that the clamping mechanisms be used to hold the device. Applicants respectfully disagree with the Office's assertion that:

> Figure 1 illustrates stabilizing a body portion within the shield/cradle member (21) solely using a digit of a user's hand and inserting an insertion member (60) of a blood extraction device (1).

Figure 1 clearly shows that the umbilical cord 68 is fastened within the device using the clamp 32. Further, as specified by Anderson:

> As shown in FIG. 1, in order to collect placental blood, the umbilical cord holder 20 is placed in a first hand 67 such that the stem 36 is located between the little and fourth fingers. The curved trough 21 then lays along the base of the fingers and adjacent to the palm. The stem allows the umbilical cord holder 20 to be easily grasped and maneuvered. The other hand, not shown, is then available to clamp the umbilical cord 68, manipulate devices such as the syringes 53 and 54, and perform other surgical procedures. The umbilical cord 68 is then placed in trough 21 so that the umbilical cord 68 extends from the placenta through uncut-end umbilical cord clamp 32, the trough 21, and the cut-end clamp 26. Clamping portions 27a and 27b of cut-end clamp 26 are then squeezed together so that male and female fasteners 28a and 28b secure together **thereby restricting the umbilical cord.** The umbilical cord is then cleansed by a suitable anti-bacterial agent. After the umbilical cord is properly cleaned, needle 70 is inserted into a vein of the umbilical cord. (Col. 5, lines 21-38)

Thus, Figure 1 and its associated description for use do not illustrate stabilizing a body portion within the shield/cradle member solely using a digit of a user's hand. On the contrary, it shows and explicitly describes "restricting the umbilical cord" using clamps 32, 26. This description is consistent with the entire Anderson reference and

nowhere in Anderson is it even suggested otherwise (i.e. that clamps be omitted and that the umbilical cord be stabilized solely using the digit of a user's hand).

Thus, it is clear from the foregoing remarks that the above-identified claims are not anticipated by the Anderson reference. Anderson does not describe each and every element of Applicants' claims. In particular, Applicants' claims 1, 16 and 34 specifically require that the method include stabilizing the umbilical cord within the shield member solely using a digit of the user's hand. Anderson, on the other hand, explicitly requires using fastening means to restrain the umbilical cord.

Accordingly, claims 1, 16 and 34 are patentable over Anderson. Claims 2-15 and 17-18 depend from claims 1 and 16 and, likewise, are patentable over Anderson. Reconsideration and withdrawal of the rejection is respectfully requested.

FOSS

Claims 19-24, 26 and 36 have been rejected under 35 U.S.C §102(b) over Foss. In particular, the Office asserts:

> Foss discloses a cradle member (24) with a substantially cylindrical cavity for releasably receiving a body portion. See col. 2, ll. 23-28. Cradle member (24) further comprises a portion (22) that is releasably held by a hand. See Fig. 2. Cradle member (24) operates as a shield to protect against needles. See col. 2, ll. 45-50. An arcuate surface recess is illustrated in Fig. 4.

Applicants respectfully submit that the rejections are moot in view of the amendments to claims 19-24, 26 and 36 herein. In particular, Applicants' shielding device is specifically designed for receiving an umbilical cord. Foss does not describe or suggest such a device.

Accordingly, claims 19-24, 26 and 36 are patentable over Foss. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

Reconsideration and allowance of claims 1, 2 and 5-37 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application.

Applicants believe that no extension of time is required since this response is being filed before the expiration of the specified time period. Applicants, however, conditionally petition for an extension of time to provide for the possibility that such a petition has been inadvertently overlooked and is required. As provided below charge Deposit Account No. **04-1105** for any required fee.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,

Date: 6/2/04

Lisa Swiszcz Hazzard (Reg. No. 44,368)
EDWARDS & ANGELL, LLP
P.O. Box 9169
Boston, MA 02209
Tel. No. (617) 517-5512